

GCS CLINICAL TRIALS

Cancer	Title	Study	Treatment	Key Criteria	Miscellaneous Criteria	Status
BREAST						
BREAST Neoadjuvant	UAB 0648	1st line Phase II Open Label	Letrazole Versus Letrazole + Avastin	<ul style="list-style-type: none"> • ER+ and/or PR+, Her2 negative • Postmenopausal • Measurable disease confirmed by mammo or US • No prior chemotherapy 	<ul style="list-style-type: none"> • No uncontrolled hypertension • No hx of thrombosis w/in 12 months 	Enrolling
BREAST Adjuvant	CIRG (TRIO) 001 / NSABP B-44-I / BO20906	1st line Phase III Open Label	Taxotere, Carboplatin and Herceptin Versus Taxotere, Carboplatin, Herceptin + Avastin	<ul style="list-style-type: none"> • HER2 positive disease confirmed by central testing • Prior total mastectomy: microscopic positive margins eligible with post tx RT • Prior breast conserving surgery (lumpectomy): negative margins plus post tx RT. • Sentinel or Axillary Lymphadenectomy 	<ul style="list-style-type: none"> • No inflammatory or contralateral breast cancer • No continued use of hormonal agent or sex hormonal tx (eligible if d/c prior to randomization) • No uncontrolled HTN • No surgery during study or 3 months post completion of Avastin • No tx with therapeutic dose of coumadin or daily tx with corticosteroids 	Enrolling
BREAST Metastatic	Novartis CRAD001Y2301	1st – 2nd line Phase III Double Blind / Placebo Controlled	Exemestane ± Everolimus	<ul style="list-style-type: none"> • ER+ and postmenopausal • PD during or within 12 months of end of adj tx w/ letrozole or anastrozole OR PD during or within 1 month of end of tx w/ letrozole or anastrozole for advanced dz • ≤ 1 prior chemo for advanced dz • ECOG ≤ 2 	<ul style="list-style-type: none"> • No HER2+ disease • No symptomatic brain mets • No metastasis of the lung as only manifestation of disease (>50% involvement) or evidence of mets estimated as more than 1/3 of the liver. 	Enrolling
BREAST Metastatic	Genentech TDM4 370g	1st – 4th line Phase III Open Label	Trastuzumab-MCC-DM1 (Immunoconjugate) Versus Xeloda + Lapatinib	<ul style="list-style-type: none"> • Her2+ disease • Prior tx with a taxane and trastuzumab • PD within 6 months of adj tx or during / after tx for advanced or metastatic dz • ECOG ≤ 1 	<ul style="list-style-type: none"> • No prior treatment with Xeloda or Lapatinib • No uncontrolled brain mets • No exclusion to number or prior therapies 	Enrolling

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BREAST Metastatic	GSK LPT111111	1st or 2nd line Phase II	Lapatinib + Nab-Paclitaxel	<ul style="list-style-type: none"> • ECOG ≤ 1 • HER2 positive disease • ≤ 1 prior chemo in metastatic setting • PD on prior taxane must occur ≥ 12 months • Prior tx w/ Herceptin permitted 	<ul style="list-style-type: none"> • No prior treatment with lapatinib • No uncontrolled brain mets (stable for at least 3 months) • Neuropathy ≤ gr 1 	Enrolling
GI						
Colorectal Metastatic	Keryx 343	3rd + line (some KRAS mutant patients may be eligible for 2nd line tx – refer to protocol) Phase III Double Blind / Placebo Controlled	Xeloda ± Perifosine	Failure of available tx defined as: <ul style="list-style-type: none"> • Failure (toxicity or PD) of Oxali based tx ≤ 12 months after completion in adjuvant setting • Failure during or within 6 months of 5FU, Irinotecan, Oxali, Avastin containing tx • Failure during or within 6 months of Erbitux or Vectibix containing tx for KRAS WT • ECOG ≤ 1 	<ul style="list-style-type: none"> • No prior exposure to XELODA unless used as a radiosensitizer, neo-adjuvant/adjuvant tx. Tx must have been completed ≥ 12 months prior to diagnosis of recurrent / mets dz • No uncontrolled brain mets 	Enrolling
Colorectal Metastatic	AMGEN SPIIRIT 20060141	2nd line Phase II Open Label	FOLFIRI + Panitumumab Versus FOLFIRI + Bevacizumab	<ul style="list-style-type: none"> • KRAS – WILD TYPE • Failure (toxicity or PD) of 1st line FOLFOX + Avastin after 4 cycles • ECOG ≤ 1 	<ul style="list-style-type: none"> • No prior CPT-11, anti-EGFR or vaccine • No brain mets • No chronic use of NSAID 	Enrolling
Colorectal Metastatic	AMGEN 20060579	2nd line Phase II Double Blind / Placebo Controlled	FOLFIRI + AMG 479 (Death Receptor) or AMG 655 (Insulin growth factor) Versus FOLFIRI	<ul style="list-style-type: none"> • KRAS – MUTANT • Failure of 1st line FOLFOX ± Avastin tx or ≤ 6 months after last dose • ECOG ≤ 1 	<ul style="list-style-type: none"> • No uncontrolled diabetes • No brain mets • No prior irinotecan based tx 	Enrolling

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Colorectal Metastatic	Daiichi CS7017-A-U203	2 nd line Phase II Open Label	FOLFIRI Versus FOLFIRI +CS-7017	<ul style="list-style-type: none"> Failure of 1st line tx (non Irinotecan based regimen) ECOG \leq 2 	<ul style="list-style-type: none"> No need for surgery or XRT during study. None of following w/in 6 months prior: diabetes mellitus requiring tx with insulin or TZD agents, MI or partial bowel obstruction No uncontrolled brain mets 	Enrolling
LUNG						
NSCLC Metastatic	ImClone C13-0811	1 st line Phase II Open Label	Gemzar + Cisplatin + Cetuximab+ IMC-A12 (Insulin growth factor) Versus Gemzar + Cisplatin + Cetuximab	<ul style="list-style-type: none"> Stage IIIB-IV NSCLC ECOG \leq 1 Prior adj tx completed \geq 6 months prior to randomization 	<ul style="list-style-type: none"> No uncontrolled brain mets No leptomenigeal disease No uncontrolled diabetes 	Enrolling
NSCLC Metastatic	Pfizer A8081007	2 nd line Phase III Open Label	Pemetrexed or Docetaxel Versus PF-02341066 (c-MET / ALK-tyk inhibitor)	<ul style="list-style-type: none"> Stage IIIB or Stage IV + translocation involving ALK gene (central testing) ECOG \leq 2 Prior tx w/ one regimen must have been platinum based 	<ul style="list-style-type: none"> If randomized to ARM B (Pemetrexed) no squamous cell histology No uncontrolled brain mets No cord compression, carcinomatous meningitis or leptomenigeal disease No uncontrolled hypertension 	Enrolling
NSCLC Metastatic	Pfizer A8081005	2 nd line + Phase II Open Label	PF-02341066 (c-MET / ALK-tyk inhibitor)	<ul style="list-style-type: none"> Stage IIIB or Stage IV + translocation involving ALK gene (central testing) ECOG \leq 2 PD on Pfizer A8081007 study Ineligible for Pfizer A8081007 study d/t > 1 prior tx for adv dz, prior tx w/ non platinum based chemo, prior docetaxel tx but have squamous cell histology (not eligible for pemetrexed) 	<ul style="list-style-type: none"> No uncontrolled brain mets No cord compression, carcinomatous meningitis or leptomenigeal disease No uncontrolled hypertension 	Enrolling

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SCLC Metastatic	UAB 0818	1 st line Phase I/IIa Open Label	Bendamustine + Irinotecan Followed by Etoposide + Carboplatin	<ul style="list-style-type: none"> Extensive stage SCLC (defined as dz not confined to one hemithorax, including ipsilateral pleural effusion or pericardial effusion) NO prior chemotherapy ECOG \leq 2 	<ul style="list-style-type: none"> No uncontrolled brain mets No neuropathy \geq grade 2 No history of chronic diarrhea 	Enrolling
PANCREATIC						
Pancreatic Metastatic	Abraxis CA046	1 st line Phase III Open Label	Gemzar Versus Gemzar + ABI-007 (Nab-Paclitaxel)	<ul style="list-style-type: none"> Prior tx w/ Gemzar ok in adjuvant setting with PD \geq 6 months after completion No prior tx for metastatic disease KPS \geq 70 Asymptomatic from jaundice and ascites prior to D1 Stable pain without requiring modification of analgesics prior to D1 	<ul style="list-style-type: none"> No islet cell neoplasms No uncontrolled brain mets (stable for \geq 3 months) No therapeutic doses of coumadin 	Enrolling
PHASE I						
Phase I Solid Tumor	Lilly LY2510924	Phase I (Northside Only)	SQ LY2510924	<ul style="list-style-type: none"> Solid Tumors, Lymphomas and CLL ECOG \leq 2 	<ul style="list-style-type: none"> No uncontrolled brain mets No acute leukemia No uncontrolled HTN 	Enrolling
Phase I Solid Tumor	ArQule ARQ197-117	Phase I (Northside Only)	IV Gemcitabine and PO ARQ197 (C-met TKI)	<ul style="list-style-type: none"> Breast, Pancreatic, Endometrial, Cholangio, and Cervical Carcinomas ECOG \leq 1 	<ul style="list-style-type: none"> No prior cancer within 3 years No significant gastrointestinal disorder No brain mets 	Enrolling
Phase I Solid Tumor	GSK EGF112930	Phase I (Northside Only)	Commercially available Lapatinib Versus Commercial Lapatinib disintegrated in water or Oral Suspension Lapatinib or Small tablet Lapatinib	<ul style="list-style-type: none"> Her2+ Metastatic Breast Solid Tumors ECOG \leq 2 	<ul style="list-style-type: none"> No uncontrolled brain mets 	Enrolling

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Phase I Solid Tumor or	GSK EGF111767	Phase Ib	Lapatinib ± Chemotherapy (per table in protocol)	<ul style="list-style-type: none"> Completed participation of GSK EGF112930 Phase I study at Northside Office 	<ul style="list-style-type: none"> No discontinuation of Lapatinib in EGF112930 study due to intolerance or treatment failure 	Enrolling
Phase I Multiple Myeloma	Immunomedics hLL1-DOX	Phase I / II (Northside Only)	hLL1-DOX (Milatuzumab – Doxorubicin Antibody Drug Conjugate)	<ul style="list-style-type: none"> MM which is refractory / relapsed to ≥2 prior tx (one tx must include thalidomide, lenalidomide or bortezomib) Karnofsky ≥70% 	<ul style="list-style-type: none"> No patients who are eligible for stem cell transplant No cumulative anthracycline exposure >300mg/m2 No prior XRT to mediastinum or pericardium No persistent toxicity ≥ gr 2 	Enrolling
HEMATOLOGY						
NHL	GSK OMG110918	Phase III	Bendamustine Versus Bendamustine + Ofatumumab (Human anti-CD20)	<ul style="list-style-type: none"> Indolent lymphoma verified to be CD20+ & measurable disease with at least 2 LN ≥ 1.5cm Indolent B-cell NHL stable or unresponsive during or w/in 6 months of tx with Rituxan ECOG ≤ 2 Prior use of bendamustine ok if completed ≥ 12months with a CR or PR of ≥ 6 months 	<ul style="list-style-type: none"> No aggressive lymphoma No previous allogenic stem cell transplant No autologous stem cell transplant, fludarabine tx or radioimmunotherapy w/in 12 months No prior XRT to pelvis No high dose steroid use ≥ 60mg qd w/in 3 months No brain mets 	Enrolling
ITP	IM-T-hA20- 07	Phase I / II	IMMU-106 (hA20) (Humanized anti- CD20 MoAb)	<ul style="list-style-type: none"> PLT ≤ 150,000 for ≥ 6 months 1 prior standard ITP tx PLT < 30,000 at screening (Phase I: PLT ≥ 10,000) 4 week stable dose of corticosteroid (≤ 20mg qd) 	<ul style="list-style-type: none"> No change in dose of danazol for 4 weeks Prior tx with Rituxan permitted, provided PR ≥ 6 months and last dose ≥ 12 months 	Enrolling

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ITP	Shionogi 0913M0621	Phase II Double Blind / Placebo Controlled with Crossover to Open Label after 6 weeks	S-888711 (TPO receptor agonist)	<ul style="list-style-type: none"> • PLT <30,000 if on no meds; <50,000 if on concomitant ITP med • 2 week stable dose of corticosteroid • 4 week stable dose of Cytosan, Danazol, CellCept, Imuran 	<ul style="list-style-type: none"> • No exposure to TPO mimetics/agonists within 4 weeks • No subjects who are unresponsive to TPO mimetics/agonists • No Campath or Stem cell therapy within 12 weeks • No Rituxan within 8 weeks • No WhinRho or IVIG within 1 week 	Enrolling
ITP	Shionogi OLE	Phase II Open Label	S-888711 (TPO receptor agonist)	<ul style="list-style-type: none"> • Completion of the 0913M0621 study • Patient who discontinued prior study d/t PLT \leq 400,000 are eligible • Continue to meet all eligibility criteria of prior study w/ PLT \leq 50,000 	<ul style="list-style-type: none"> • Withdrawal from prior study 	Enrolling
Observation	Novartis GIST	Observational	Observational	<ul style="list-style-type: none"> • Open to all GIST patients 		Enrolling
Observation	Novartis CML	Observational	Observational	<ul style="list-style-type: none"> • Confirmed CML within past 6 months 		Enrolling
Observation	Celgene MM	Observational	Observational	<ul style="list-style-type: none"> • Newly diagnosed and symptomatic Multiple Myeloma • \geq 18 years old 	<ul style="list-style-type: none"> • No participation in a clinical trial where study treatment is blinded 	Enrolling
Observation	Sanofi-Aventis Prostate	Observational	Observational	<ul style="list-style-type: none"> • Castrate resistant prostate cancer patients with PD during first course of 1st line Taxotere tx or after at least 3 cycles of 1st line Taxotere tx. 	<ul style="list-style-type: none"> • No participation in clinical trial for 2nd line tx (2nd line tx has to be any tx other than clinical trial) • Participation in clinical trial for 3rd line + is permitted 	Enrolling
Observation	Allos PTCL	Observational	Observational	<ul style="list-style-type: none"> • Newly diagnosed Peripheral T-Cell lymphoma • Enrollment into registry within 30 days of starting tx for initial diagnosis of PTCL. 	<ul style="list-style-type: none"> • No Precursor T/NK neoplasms, T-cell large granular lymphocytic leukemia, mycosis fungoides, other than transformed mycosis fungoides, Sezary syndrome, Primary cutaneous CD30+ disorders: ALCL and lymphomatoid papulosis 	Enrolling